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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,863	10/12/2001	Chad A. Mirkin	00-713-i19	2841

7590 11/24/2003

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EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,863	MIRKIN ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 433-436 and 481-556 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 433-436, 481-491 and 511-556 is/are allowed.
- 6) ☒ Claim(s) 492-499 is/are rejected.
- 7) ☒ Claim(s) 500-510 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/17/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

1. Applicants' arguments and amendments, filed on 10/17/03, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 492-499 are rejected under 35 U.S.C. 102(e) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Yguerabide et al. (6,214,560).

5. The applicants have the arguments that the reference does not teach recognition oligonucleotide. This is not convincing because Yguerabide teaches n certain analytical and diagnostic assays, it may be preferable to increase the detectability of the scattered light properties of the particles so that very simplified or no detection instrumentation is required. By use of the appropriate molecular recognition binding-pairs and particles it is possible to significantly increase the level of detection sensitivity. Single-stranded homopolymer sequences, and other binding-pair systems can be used to "chain-together" and "build-up" many particles (col 73-76).

Further, the reference describes methods of attachment of substances to particles and other surfaces. In this method of attaching substances to particles or other surfaces, a two step approach which involves the use of base material molecules is used. Suitable base material molecules are any substance which can approach and interact with the surface by adsorption or other chemical process, and have accessible functional groups to which additional substances, as for example, binding agents can be attached. As an example, the reference has used a derivative of a polyethylene glycol. The properties of this molecule allow for its use as a base material molecule. Each molecule of this polymer has four amine groups which can serve as linkage sites for the conjugation of additional substances. The hydrophobic backbone of the polyethylene derivative interacts with the particle and is attached to the particle surface by adsorption or some other process. This interaction is very strong. The amine groups do not appear to interact with the particle surface and are accessible as conjugation sites for the attachment of additional substances as for example, binding agents. Using this polymer as the base molecule they have prepared two different types of particle-binding agent reagents. One reagent contains biotin groups as binding agents and the other particle-binding agent reagent was made to contain single-stranded nucleic acids as binding agents. The biotin used for attachment was a chemically modified form where it will covalently link to amine groups. For the nucleic acids, the 5' ends were chemically modified so that they would chemically react with the amine groups. Linker arms of various lengths and composition can also be incorporated into the molecular structure. For example, a small molecular weight base material molecule can be used where its

molecular structure is optimized for attachment to the particle or surface, attachment of most any substance to it with any desired orientation, and with a high level of binding activity. As an example, a linear polypeptide twenty amino acids in length is chemically modified at one terminus by the addition of disulfide or thiol chemical groups. The native polypeptide is composed of amino acids such that the polypeptide chain will not interact with the surface except through the chemically modified end. At the other terminus a free amino group exists, or alternatively, has been chemically modified for a desired conjugation process such that most any substance can be attached at this position. This low molecular weight base material molecule then is used in one or more variations of the methods as described herein. (col 77-81). The polyethylene glycol or the polypeptide is viewed to be inclusive of the spacer portion of instant claim 243 for example. And the amine group is viewed to be inclusive of the functional group.

6. Claims 500-510 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 433-436, 481-491, 511-556 are allowed.

8. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855, **(Please note that starting after January 20th, 2004, the examiner's new phone number will be 571-272-0786)**. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Friday, November 21, 2003


JEZIA RILEY
PRIMARY EXAMINER